

Serial No. 10/659,735  
Docket No. SHE0064.00**RECEIVED****CENTRAL FAX CENTER****MAR 25 2008****I. Introductory Comments**

In the Office Action under reply, the Examiner rejected the claims as follows: under 35 U.S.C. §102(b) as allegedly being anticipated by Bergstrom et al. (WO 99/32424) (claims 28-30, 38-44, 46, 47, 49, 52 and 53); and under 35 U.S.C. §103(a) as allegedly being anticipated by Bergstrom et al. (WO 99/32424) in view of Hunter et al. (U.S. Patent No. 5,763,538) and Baker (U.S. Patent No. 5,634,971) (claims 28, 42-44 and 54).

**II. Status of the Claims**

Claims 28-30, 38-44, 46-49, 53 and 54 were previously pending.

Claims 28, 47, 48 and 54 have been amended and claim 46 has been canceled with the ability to prosecute the previously pending subject matter in one or more applications. Thus, claims 28-30, 38-44, 47-49, 53 and 54 remain under consideration.

Support for the changes to the claims is identified below. Additional support other than that identified below may exist in the originally filed application for one or more changes to the claims.

Claim 28 has been amended to recite a nominal average molecular weight range for the water-soluble polymer segment, wherein support for the range having a low end point of from about 2,000 daltons is found on page 30, line 23, of the originally filed specification, and a high end point of to about 100,000 daltons is found on page 30, line 22, of the originally filed specification.

Claims 47 and 48 have been amended to recite a nominal average molecular weight (rather than "mass") in order to better reflect the convention of using the term weight when referencing a polymer's size.

Claim 54 has been amended to remove the extraneous article "the" in order to improve the syntax of the claim.

As support for the changes is found in the application as filed, no new matter is introduced by the entry of the above-identified changes. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

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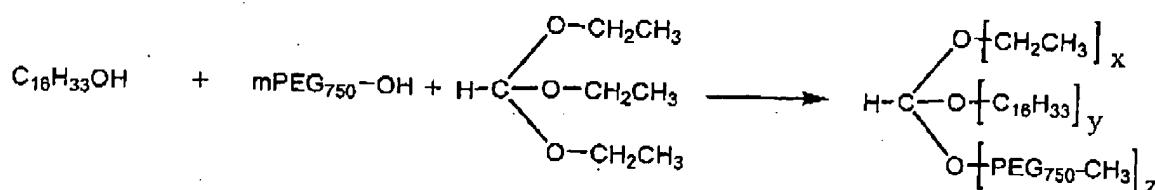
### III. The Rejection Under 35 U.S.C. §102(b)

The Examiner has rejected claims 28-30, 38-42, 46, 47, 49 and 53 under 35 U.S.C. §102(b) as allegedly being anticipated by Bergstrom et al. (WO 99/32424). Ostensibly, the Examiner has taken the position that each and every element of rejected claims is disclosed by Harris et al.

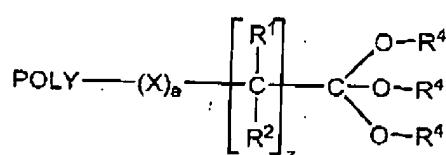
The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. See *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

In response to Applicant's previous argument that the claimed subject matter can be distinguished over the disclosure of Bergstrom et al., the Examiner -- while acknowledging that "R" is defined by the reference as "C<sub>1-7</sub> atoms" (and therefore not a water-soluble polymer segment) -- cites Examples 1-6 of Bergstrom et al. to describe a reaction of triethyl orthoformate with methyl capped PEG in support of the rejection.

A close reading of the Examples 1-6 of Bergstrom et al., however, reveals that the reference still fails to disclose the subject matter encompassed by Applicant's claims. For example, Example 6 appears to teach reacting hexadecanol, monomethyl-blocked polyethylene glycol having a mean molecular weight of 750 and triethyl orthoformate. Schematically, the reaction can be represented as follows.



Such a reaction does not disclose a polymer having the following structure:



wherein:

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POLY is a water-soluble polymer segment having a nominal weight average molecular weight of from about 2,000 daltons to about 100,000 daltons;

(a) is either zero or one;

X, when present, is a spacer moiety;

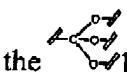
(z) is an integer from 1 to 24;

R<sup>1</sup>, in each occurrence, is independently H or an organic radical selected from the group consisting of alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, and substituted aryl;

R<sup>2</sup>, in each occurrence, is independently H or an organic radical selected from the group consisting of alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, and substituted aryl; and

each R<sup>4</sup> is either (i) an organic radical independently selected from the group consisting of alkyl, substituted alkyl, alkenyl, substituted alkenyl, alkynyl, substituted alkynyl, aryl, and substituted aryl, or (ii) one or more atoms that combine with another R<sup>4</sup> or the remaining R<sup>4</sup> moieties to form a cyclic ortho ester structure.

At a minimum, Bergstrom et al.'s examples and disclosure show that the *location* of any water-soluble polymer segment would be *proximate* to one of the three oxygen atoms in



the branched structure and not distal thereto. Moreover, none of the Examples of Bergstrom et al. teaches use a water-soluble polymer segment having a nominal weight average molecular weight of from about 2,000 daltons to about 100,000 daltons in any location or orientation, much less in the location required by Applicant's claims.

Finally, the Examiner points to page 5, lines 9-12, as allegedly teaching that the hydrophilic part is preferably derived from polyethylene glycols. Applicant notes that the molecular weight recited at the end of the passage (between 100 and 2000) appears to modify the size of the end capping group, rather than the size of the whole polymer.

For at least these reasons, Bergstrom et al. fails to disclose each and every feature of independent claim 28 (upon which each of claims 29, 30, 38-42, 46, 47, 49 and 53 depend, either directly or indirectly). Consequently, reconsideration and removal of the rejection under 35 U.S.C. §102(b) are respectfully requested.

#### IV. The Rejection Under 35 U.S.C. §103(a)

The Examiner has rejected claims 28, 42-44 and 54 under 35 U.S.C. §103(a) as allegedly being unpatentable over Bergstrom et al. (WO 99/32424) in view of Hunter et al. (U.S. Patent No. 5,763,538) and Baker (U.S. Patent No. 5,634,971).

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The standard for obviousness was provided in a previous response.

The Examiner alleges that the "ortho ester is provided by Bergstrom and Hunter and Baker are relied upon for teaching polyethylene glycol can be endcapped with ethoxy and methoxy (Hunter) and methyl (Baker)."

These additional references, however, do not remedy the deficiencies of Bergstrom et al. For example, neither Hunter et al. and Baker teaches or suggests ortho ester functional groups, much less teaching or suggesting the location of a water-soluble polymer segment at a particular location relative to an ortho ester functional group. As pointed out above in Section III., Bergstrom et al. also fail to teach these features as well.

As a result, the obviousness rejection of claims of 28, 42-44 and 54 under 35 U.S.C. §103(a) is unsustainable. Reconsideration and withdrawal of the rejection for at least the reasons provided above are respectfully requested.

#### V. Conclusion

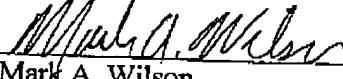
In view of the foregoing, Applicant submits that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections are respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted on behalf of  
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Date: March 25, 2008

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